

1033430

NOV - 7 2003

**Summary of Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

<b>Submitter</b>	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
<b>Contact</b>	Tamara Nelson International Regulatory Affairs Specialist Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-776-6852 Email <a href="mailto:tnelson@3implant.com">tnelson@3implant.com</a>
<b>Date Prepared</b>	October 24, 2003
<b>Device Name</b>	3 <i>i</i> TG OSSEOTITE® Wide Implants
<b>Classification Name</b>	Endosseous Dental Implant
<b>Device Classification</b>	Class III Dental Devices Panel 21 CFR § 872.3640
<b>Predicate Devices</b>	TG OSSEOTITE® Dental Implants K972444 OSSEOTITE® IOL Implants K031632
<b>Performance</b>	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
<b>Device Description</b>	The 3 <i>i</i> TG OSSEOTITE® Wide Implants are trans-gingival implants designed with an internal morse-taper. The wider dimension of the seating surface provides a realistic size proportion of a natural tooth of the posterior area.

**Indications for Use**

The *3i* TG OSSEOTITE® Wide Implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.

**Technological Characteristics**

The *3i* TG OSSEOTITE® Wide Implants contain features and functions which are similar to the currently available TG OSSEOTITE® Implants.

**Conclusion**

The *3i* TG OSSEOTITE® Wide Implants are substantially equivalent to the legally marketed TG OSSEOTITE® Implants.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Tamara Nelson  
International Regulatory Affairs Specialist  
Implant Innovations, Incorporation  
4555 Riverside Drive  
Palm Beach Gardens, Florida 33410

Re: K033430

Trade/Device Name: 3I TG Osseotite Wide Implants, Models TG685, TG610, TG611, TG613  
Regulation Number: 872.3640  
Regulation Name: Dental Implant  
Regulatory Class: III  
Product Code: DZE  
Dated: October 27, 2003  
Received: October 28, 2003

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

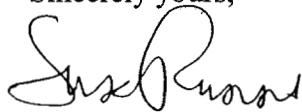
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Implant Innovations, Inc.**  
**Special 510(k) Premarket Notification – TG OSSEOTITE Wide Implant: Device Modification**

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**510(k) Number (if known): K033430**

**Device Name: 3i TG OSSEOTITE® Wide Implants**

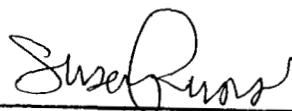
**Indications for Use:**

3i dental implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K033430

Prescription Use: ✓  
(Per 21 CFR 801.109)

OR

Over the Counter Use: \_\_\_\_\_

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